NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC Plaintiffs, v. SANDOZ, INC. Defendant.	Case No. 3:18-cv-14895-BRM-DEA **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before this Court are the applications by Plaintiffs Par Pharmaceutical, Par Sterile Products, LLC, and Endo Par Innovation Company, LLC ("Par" or "Plaintiffs") and Defendant Sandoz ("Sandoz" or "Defendant") for claim construction to resolve disputes over the construction of four claim terms[1]: "administering"; "vasopressin"; "wherein the impurities are determined based on"; and "consists essentially of."[2]

[1] The moving papers focus on five claims, but Par and Sandoz submitted an agreed upon construction of the term "wherein the humans' mean arterial blood pressure is increased within 15 minutes of administration" on January 8, 2020. (ECF No. 72.)

[2] The patents-in-suit are U.S. Patent Nos. 9,375,478 ("'478 patent"), 9,687,526 ("'526 patent"), 9,750,785 ("'785 patent"), 9,744,209 ("'209 patent"), and 9,937,223 ("'223 patent") (collectively, the "patents-in-suit"). They are all from the same patent family and are continuations or continuations-in-part from the same ultimate parent application (US Application No. 14/610,499). Additionally, the parties stipulated to dismiss all claims, counterclaims, and defenses relating to U.S. Patent No. 9,744,239 ("'239 patent"). (ECF No. 90.)

This Court has examined the disputes over the construction of these claim terms and, on January 21, 2020, held a hearing pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). For the reasons set forth in this Opinion, this Court defines the three of the four disputed claim terms as follows: (1) "administering" has its plain and ordinary meaning; (2) "vasopressin" means "arginine vasopressin as described in SEQ. ID. No. 1"; and (3) "wherein the impurities are determined based on" means "wherein any determination as to whether the pharmaceutical composition includes the specified impurities is to be made via the recited procedure." Finally, the Court has deferred its decision on the "consists essentially of" claim term until a more complete record is developed.

I. BACKGROUND

A. Factual Background

This case arises out of an action for patent infringement instituted by Par against Sandoz. Par is a New York corporation that develops, manufactures, and markets pharmaceutical products in the United States. (Am. Compl. (ECF No. 8) ¶ 1.) Sandoz is a Colorado corporation that markets pharmaceutical products in the United States. (*Id.* ¶ 4.)

Between June 28, 2016 and April 10, 2018, the United States Patent and Trademark Office ("PTO") duly and legally issued all five patents-in-suit, each entitled "Vasopressin Formulations for Use in Treatment of Hypotension." (*Id.* ¶ 14-19.) On or about August 21, 2018, Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 212069 (the "Sandoz ANDA") pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic vasopressin injection referencing Par's VASOTRICT products as the reference listed drug. (*Id.* ¶ 28.)

Claims from four of the patents-in-suit contain the four disputed terms. Claim 1 of the '223

patent reads:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous **administration** comprising:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of **vasopressin** or a pharmaceutically acceptable salt thereof;
> ii) acetate buffer; and
> iii) water; wherein the pharmaceutical composition has a pH from about 3.7 to about 3.8;
> wherein the pharmaceutical composition is provided in a container;
> b) puncturing a dispensing region of the container a first time and drawing from the container a portion of the pharmaceutical composition;
> c) intravenously **administering** the portion of the pharmaceutical composition to the human; wherein:
> the human is hypotensive;
> d) puncturing the dispensing region of the container a second time and drawing from the container a second portion of the pharmaceutical composition; wherein:
> the second time that the dispensing region of the container is punctured occurs at least 48 hours after the first time that the dispensing region of the container is punctured;
> e) intravenously **administering** the second portion of the pharmaceutical composition to the human; wherein:
> the administration of the second portion of the pharmaceutical composition provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 unites of vasopressin or the pharmaceutically acceptable salt thereof per minute.

(ECF No. 1 ¶ 45 (emphasis added).)

Claim 1 of the ’478 patent reads:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising **administering** to the human in a unit dosage form, wherein the unit dosage form **consists essentially of:**
> a) from about 0.01 mg/mL to about 0.07 mg/mL of **vasopressin** or a pharmaceutically-acceptable salt thereof;
> b) 10 mM acetate buffer; and
> c) water; wherein:
> the unit dosage form has a pH of 3.8;
> the administration provides to the human from about 0.01 units of

> **vasopressin** or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive

(ECF No. 1 ¶ 53 (emphasis added).)

Claim 1 of the '526 patent reads:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration comprising:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> ii) acetic acid; and
> iii) water; wherein:
> the pharmaceutical composition has a pH of 3.8;
> b) storing the pharmaceutical composition at 2-8° C. for at least 4 weeks; and
> c) intravenously **administering** the pharmaceutical composition to the human; wherein:
> the administration provides to the human from about 0.01 units of **vasopressin** or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; wherein:
> the human is hypotensive; wherein:
> the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

(ECF No. 1 ¶ 61 (emphasis added).)

Claim 1 of the '785 patent reads:

> Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of **vasopressin** or a pharmaceutically acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the
> impurities have from about 85% to about 100% sequence homology to **SEQ ID NO.: 1,** and wherein the unit dosage form has a pH of 3.7-3.9.

(ECF No. 1 ¶ 69 (emphasis added).)

Claim 1 of the '209 patent reads:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising **administering** to the human a unit

> dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:
> the unit dosage form has a pH of 3.7-3.9;
> the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive

(ECF No. 1 ¶ 77 (emphasis added).)

Additionally, the chart below sets forth the parties' proposed constructions.

Terms as used in Claims	**Asserted Claims**	**Par Construction**	**Sandoz Construction**
"administering to the human a unit dosage form"	'478 claim 1; '209 claim 1	Ordinary meaning, no construction necessary	Administering to the human a unit dosage form having the properties recited in the claim
"intravenously administering the pharmaceutical composition to the human"	'526 claim 1	Ordinary meaning, no construction necessary	Intravenously administering the pharmaceutical composition having the properties recited in the claim to the human
"intravenously administering the portion [/second portion] of the pharmaceutical composition to the human"	'223 claim 1	Ordinary meaning, no construction necessary	Intravenously administering the portion[/second portion] of the pharmaceutical composition having the properties recited in the claim to the human
"administering the diluted unit dosage form to the human by intravenous administration	'239 claim 1	Ordinary meaning, no construction necessary	Unit dosage form having the properties recited in the claim to the human by intravenous administration

"vasopressin"	All asserted claims of all patents	Arginine vasopressin as described in SEQ. ID. No. 1	Plain and ordinary meaning
"wherein the impurities are determined based on	'209 claim 11, '785 claim 2	Ordinary meaning, no construction necessary	This phrase requires a step of determining the impurities based on the HPLC method recited in the claim
"consists essentially of"	'478 claim 1;	Ordinary meaning, no construction necessary	Indefinite

B. Procedural History

On October 11, 2018, Par filed a Complaint (the "Complaint") against Sandoz asserting infringement of the patents-in-suit. (ECF No. 1.) On the same day, Par filed an Amended Complaint (the "Amended Complaint"). (ECF No. 8.) On December 12, 2018, Sandoz filed an Answer to the Amended Complaint as well as counterclaims asserting the noninfringement and invalidity of the patents-in-suit. (ECF No. 11.)

On August 28, 2019, both Par and Sandoz filed their opening *Markman* briefs. (ECF Nos. 52 & 53.) On October 28, 2019, both Par and Sandoz filed their *Markman* reply briefs. (ECF Nos. 63 & 64.) On January 21, 2020, this Court held a *Markman* hearing, at the conclusion of which this Court ordered supplemental briefing on the disputed claim terms. (ECF No. 81.) On January 31, 2020, the parties simultaneously submitted supplemental claim construction briefs. (ECF Nos. 88 & 89.)

II. LEGAL STANDARD

Claims define the scope of the inventor's right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope and is a determination reserved exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995) (*en banc*). Indeed, the court can only

interpret claims and "can neither broaden nor narrow claims to give the patentee something different than what it has set forth" in the specification. *E.I. Du Pont de Nemours v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1998). A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art. *Dow Chem. Co. v. Sumitomo Chem Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Markman v. Westview Instruments*, 52 F.3d 967, 986 (Fed. Cir. 1995) (*en banc*), *aff'd*, *Markman*, 517 U.S. 370 (holding that "[t]he focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the terms to mean"); *Phillips*, 415 F.3d at 1312-13. In construing the claims, the court may examine both intrinsic evidence (e.g., the patent, its claims, the specification, and the prosecution history) and extrinsic evidence (e.g., expert reports and testimony). *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999).

The analysis of claim language begins with determining the "ordinary and customary meaning of a claim term[, which] is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313. Further, the language should not be read solely in the context of the claim under review; instead, it should be analyzed "in the context of the entire patent" and with an understanding of how that language is used in the field from which the patent comes. *Id.* In conducting this review, a different interpretation is placed on a term located in an

independent claim than on those located in dependent claims, and it is understood that each claim covers different subject matter. *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1331 (Fed. Cir. 2007) (quoting *Phillips*, 415 F.3d at 1315 (holding that the "presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim")).

In reviewing the language of a patent, "the court starts the decision-making process by reviewing the same resources as would [a person or ordinary skill in the art in question], *viz.*, the patent specifications and the prosecution history." *Phillips*, 415 F.3d at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). When "the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent," understanding claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful" to explain the terms used. *Id.*

Often times, however, the ordinary meaning of the claim language is not readily apparent, and in such circumstances, courts look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Id.* Those sources may include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* Furthermore, claims must be read in view of the claim specification, which is of seminal importance in providing framework for understanding the claim language. As the Federal Circuit in *Markman* explained:

> The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define

> terms used in the claims. As we have often stated, a patentee is free to use his [or her] own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification. The written description part of the specification itself does not delimit the right to exclude. That is the function and the purpose of the claims.

Markman, 52 F.3d at 979-80.

This Court's reliance on the specification is appropriate given the Patent and Trademark Office's rules requiring "that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent bases in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'" *Phillips*, 415 F.3d at 1316-17 (quoting 37 C.F.R. § 1.75(d)(1)). During this analysis, however, courts should not "import limitations from the specifications into the claims." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quoting *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005)).

The patent's prosecution history is also of "primary significance in understanding the claims." *Markman*, 52 F.3d at 980. "The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317. Further, the prosecution history is also relevant to determining whether the patentee disclaimed or disavowed the subject matter, thereby narrowing the scope of the claim terms. *Seachange Int'l, Inc. v. C-Cor Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005).[3]

[3] "[I]n certain cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006) (quoting *Phillips*, 415 F.3d at 1316) (internal citations omitted). In such cases, the Federal Circuit interprets the claim more narrowly than it otherwise would in order to give effect

In addition to intrinsic evidence, a court may also rely on extrinsic evidence in interpreting a claim. *Phillips*, 415 F.3d at 1317. Extrinsic evidence consists of "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.* (citations omitted). However, while extrinsic evidence "can shed useful light on the relevant art," it is "less significant that the intrinsic record in determining the legally operative meaning of claim language." *Id.* Extrinsic evidence should be "considered in the context of intrinsic evidence," as there are flaws inherent in the exclusive reliance on extrinsic evidence, including, *inter alia*, biases, inadvertent alterations of meanings, and erroneous contextual translations. *Id.* at 1318-19. Furthermore, extrinsic evidence should not be relied upon where "an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

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to the patentee's intent to disavow a broader claim scope. *Ventana*, 473 F.3d at 1181 (citing *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319-20 (Fed. Cir. 2006); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1342-44 (Fed. Cir. 2001)). However, pointing solely to "general statements by the [patentee] indicating that the invention is intended to improve upon prior art" will not demonstrate that the patentee intended to "disclaim every feature of every prior art device discussed in the 'BACKGROUND ART' section of the patent." *Ventana*, 473 F.3d at 1181; *see also Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) ("Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.")

Moreover, the Federal Circuit has found it "particularly important not to limit claim scope based on statements made during prosecution '[a]bsent a clear disavowal or contrary definition.'" *Digital Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1273 (Fed. Cir. 2012) (citing *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1286 (Fed. Cir. 2011) (quoting *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004))). The reason for such a stringent rule is "because the prosecution history represents an ongoing negotiation between the PTO and the application," and "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Digital Vending*, 672 F.3d at 1273 (quoting *Phillips*, 415 F.3d at 1317).

III. DECISION

This Court addresses the interpretation of the four disputed terms in the patents-in-suit—"administering," "vasopressin," "wherein the impurities are determined based on," and "consists essentially of"—in turn.

A. The Meaning of "administering"

Par proposes that "administering" be construed to have an ordinary meaning, with no construction necessary (ECF No. 52 at 12) whereas Sandoz proposes that "administering" be construed to mean "administering to the human a unit dosage form having the properties recited in the claim" for the '478 and '209 patents, "intravenously administering the pharmacist composition having the properties recited in the claim to the human" in the '526 and '223 patents, and "administering the diluted unit dosage form having the properties recited in the claim to the human by intravenous administration" in the '239 patent. (ECF No. 53 at 11-12.)

Par contends Sandoz's proposed construction of the "administering" terms would "exclude administering the claimed vasopressin composition in the manner in which vasopressin compositions are nearly always administered." (ECF No. 52 at 13.) Specifically, Par contends "Sandoz's attempt to exclude administration via an IV drip" contradicts the plain meaning of the claims, contradicts other claims in the patents, and would exclude the preferred and only embodiments expressly taught in the patents. (*Id.*)

Conversely, Sandoz contends Par's proposed construction of the "administering" terms to cover administration of a diluted formula "fails in view of the claims, specifications, and prosecution histories of the patents-in-suit." (ECF No. 53 at 14.)

Instructive in analyzing this dispute is Judge Connolly's decision in *Par Pharm., Inc. et al. v. Eagle Pharms. Inc.*, No. 18-823 (D. Del. July 1, 2019). In his *Markman* ruling, Judge Connolly

also analyzed the term "administering" from the same patents as the patents-in-suit. (ECF No. 52, Ex. 8 at 59-61.) In that case, defendants proposed virtually the same construction as Sandoz currently proposes along with a parenthetical stating the construction "does not permit dilution before administration." (ECF No. 52, Ex. 9 at 5.)

Sandoz contends they "do not seek to exclude administration of diluted dosage forms from its proposed construction." (ECF No. 64 at 21.) Rather, Sandoz proposes the "administering" terms mean a vasopressin administration with properties required by the claims, regardless of whether the formulation was created through dilution. (*Id.*) At the *Markman* hearing, Sandoz pointed to certain embodiments that did not mention dilution and contrasted them with embodiments that do mention dilution. (*See, e.g.*, Sandoz Markman PowerPoint at 18.) In so doing, Sandoz argued that embodiments that do not expressly mention dilution exclude the diluted form of administration. (*Id.* at 18-19.) However, this Court—in accordance with Judge Connolly's opinion—does not agree with Sandoz's proposed construction.

As stated in Judge Connolly's ruling—and later affirmed by the Federal Circuit's decision in *Eli Lilly and Co v. Hospira, Inc.*, 933 F.3d 1320 (Fed. Cir. 2019)—the ordinary meaning of "administering" encompasses the administration of vasopressin after it has been dissolved in solution. (*See* ECF No. 52, Ex. 8 at 59-61); *see also Eli Lilly*, 933 F.3d at 1329. In so ruling, Judge Connolly expressly rejected an argument identical to Sandoz's current contention. *Par Pharm., Inc.*, No. 18-823.

For the reasons stated above, the Court defines "administering" as having its ordinary meaning.

B. The Meaning of "vasopressin"

Par proposes "vasopressin" be construed as "arginine vasopressin as described in SEQ. ID. No. 1" (ECF No. 52 at 22) whereas Sandoz proposes "vasopressin" be construed as having its plain and ordinary meaning. (ECF No. 53 at 34.)

In proposing its construction, Par contends it has "acted as its own lexicographer" and expressly defined "vasopressin" in the specifications of the patents-in-suit. (ECF No. 52 at 23.) Specifically, Par contends—both in its moving papers and at oral argument—the patents-in-suit include a four page "sequence listing" that "sets forth the chemical formula and structure for the various peptides described in the patents." (ECF No. 88 at 7.)

"When a patentee acts as its own lexicographer, that definition governs." *Continental Circuits LLC v. Intel Corp*., 915 F.3d 788, 796 (Fed. Cir. 2019) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)). Here, Par has provided a clear definition of "vasopressin" as "a nonapeptide." (ECF No. 88, Ex. A at 35-37.) Additionally, the reference SEQ. ID. No. 1 contains an illustration of the structure and specifically refers to vasopressin as "arginine vasopressin." (*See* ECF No. 88 at 10.) Furthermore, at oral argument, Sandoz conceded that the placement of "Arg" within the illustration of the chemical compound made clear the diagram displayed arginine vasopressin. Because Par specifically defines "vasopressin" by reference to SEQ. ID. No. 1 which states the compound is synthetic arginine vasopressin, that definition governs.

For the reasons set forth above, the Court defines "vasopressin" as "arginine vasopressin as described in SEQ. ID. No. 1."

C. The Meaning of "wherein the impurities are determined based on"

Par proposes that "wherein the impurities are determined based on" to be construed to have an ordinary meaning (ECF No. 52 at 26) whereas Sandoz proposes that "wherein the impurities

are determined based on" be construed to require a step of determining the impurities based on the HPLC method recited in the claim. (ECF No. 53 at 21.)

Par contends the disputed term appears in two dependent claims—claim 2 of the '785 patent and claim 11 of the '209 patent—that refer directly back to independent claims in their respective patents. (ECF No. 52 at 27.) The independent claim describes the pharmaceutical properties that are required to infringe while the dependent claims specify how to demonstrate that a particular formulation has the infringing properties. (*See* ECF No. 88 at 13.) Therefore, based on Par's proposed construction, a formulation will infringe if it has the properties described in the independent claim regardless of whether the HPLC method described in the dependent claim is actually used. (*Id.*)

Sandoz, however, contends the present tense "are determined" indicates that using the HPLC method to determine a formulation's properties is a required step in infringement. (ECF No. 53 at 22.) The Court disagrees.

Instructive in this decision is *Horizon Pharma Ireland Ltd. v. Actavis Labs., UT, Inc.*, No. 15-07742, 2016 WL 4432681 (D.N.J. Aug. 17, 2016). There, the court found a similar "wherein" clause to "simply describe[] the nature of [the] formulation." *Id.* at *3. Additionally, the court found—notwithstanding the use of the present tense ("is administered")—the construction "stays true to the claim language" and avoids turning the composition claims into method claims. *Id.* Therefore, this Court finds the "wherein" claims to be dependent composition claims rather than method claims.

For the reasons stated above, the Court defines "wherein the impurities are determined based on" as having its ordinary meaning.

D. The Meaning of "consists essentially of"

Par proposes that "consists essentially of" be construed to have its ordinary meaning (ECF No. 52 at 30) whereas Sandoz proposes that "consists essentially of" is indefinite. (ECF No. 53 at 24.)

To prove indefiniteness, a party must show by clear and convincing evidence that the asserted claims, viewed in light of the specification and prosecution history, fail to "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.* 572 U.S. 898, 899 (2014). However, it is the typical practice of courts in this Circuit to defer consideration of an indefiniteness challenge until time for summary judgment or trial, when there is a fully developed expert record. *See, e.g. Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 17-9105, 2019 WL 20067373, at *10 (D.N.J. May 9, 2019) ("[T]his Court address invalidity disputes, of which indefiniteness is one, at summary judgment or at trial."); *Adapt Pharma Operations Ltd. v. Teva Pharm. USA, Inc.*, No. 16-7721, 2019 WL 1789463, at *4 (D.N.J. Apr. 24, 2019) (deferring decision on an indefiniteness challenge until the presentation of expert testimony). Indeed, the Court raised the issue of the need for expert testimony at the *Markman* hearing.

> MS. LYDIGSEN: We believe that exists here based on the specification itself, however, and there's no need for expert testimony. Their own patent specification makes -- fails to disclose the basic and novel properties with sufficient clarity for a person of ordinary skill to identify them.
>
> THE COURT: Who tells me that?
>
> MS. LYDIGSEN: Who tells you that?
>
> THE COURT: Yes. You?
>
> MS. LYDIGSEN: It should be apparent from the specification. It should be reading the specification. There's no reason why we need an expert mouthpiece to read the

> patent specification.
>
> THE COURT: To say what a POSA would interpret this or how a POSA would read that, I don't need an expert for that?
>
> MS. LYDIGSEN: Not for identification of the basic and novel properties.

Unofficial Transcript of Jan. 21, 2020 *Markman* Hearing at 40:22-25 to 41:1-14.

However, despite its previous assertions, Sandoz now agrees with the above and requests this Court defer ruling on the indefiniteness challenge. (ECF No. 89 at 11.) Therefore, in accordance with other courts from this Circuit, this Court will defer its decision on this issue until a more complete record is developed.

IV. CONCLUSION

For the reasons set forth above, this Court defines three of the disputed claim terms as follows: (1) "administering" has its plain and ordinary meaning; (2) "vasopressin" means "arginine vasopressin as described in SEQ. ID. No. 1"; and (3) "wherein the impurities are determined based on" means "wherein any determination as to whether the pharmaceutical composition includes the specified impurities is to be made via the recited procedure." Finally, the Court has deferred its decision on the "consists essentially of" claim term until a more complete record is developed.

Date: March 9, 2020

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE